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APR 03 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is furnished in accordance with requirements detailed in 21 CFR 807.92.

1.

Assigned 510(k) number K-130757:

Submitter's Identification:

Spencer Fillmore
2410 S Sumner Lane
Greenacres, WA 99016

Correspondence:

Christina Bernstein
BB Medical Surgical, Inc.
2670 Leavenworth Street
San Francisco, CA 94133
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Date of Response: 20 March 2014

2.

Device name:

i) Extension Tubes

Proprietary name: Kobold Secure Lock Transfer Guide Tube Set™

- A. Regulation Section 892.5700
- B. Classification: Class II
- C. Product Code: JAQ
- D. Panel: Radiology

ii) Needle Extender Sets

Proprietary name: Kobold Interstitial Extender Set™

A. Regulation Section 892.5700

B. Classification: Class II

C. Product Code: JAQ

D. Panel: Radiology

3.

Intended Use:

i) Kobold Secure Lock Transfer Guide Tube Set™

The Secure Lock transfer guide tubes have been developed to enable the connection of Varian's VariSource iX and 200 afterloaders to HDR applicators. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient's tumor site.

Secure Lock Guide Tube Sets are non-invasive products that have no direct patient contact.

ii) Kobold Interstitial Extender Set™

The interstitial extenders have been developed to enable the connection of Varian or Kobold Transfer Tubes to Kobold Interstitial Needles. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient's tumor site. All Kobold Interstitial Extenders™ are intended for single use and are disposable.

Interstitial Extenders are non-invasive products that have no direct patient contact.

4.

Device Description:

i) Kobold Secure Lock Transfer Guide Tube Set™

Each tube is numbered to ensure correct connection of the applicator channel with the corresponding afterloader channel. Only a physician who has been trained in the appropriate afterloader systems should use the Secure Lock transfer guide tubes. These transfer guide tubes are compatible with VariSource iX and VariSource 200 afterloaders.

ii) Kobold Interstitial Extender Set™

Each extender is numbered to ensure correct connection of the interstitial extenders and corresponding (1) transfer guide tube and (2) interstitial needle. Only a physician who has been trained in the appropriate afterloader systems should use the interstitial extenders.

5.

Substantial Equivalence Information:

i) Kobold Secure Lock Transfer Guide Tube Set™

Information presented supports substantial equivalence of the Kobold Secure Lock Transfer Guide Tube Set™ to the predicate device. The device has the same indications for use, has similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same cleaning and disinfecting procedures.

A. Predicate device name: Intracavity Brachytherapy Applicators

B. Predicate K-Number: K-113766

C. Comparison with predicate:

SUBSTANTIAL EQUIVALENCE TABLE	KOBOLD LLC	VARIAN®, INC.
K-Number	130757	113766
Device Description	Transfer Tube Set	Transfer Tube Set
Indications For Use	<p>The Secure Lock transfer guide tubes have been developed to enable the connection of Varian's VariSource iX and 200 afterloaders to HDR applicators. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient's tumor site.</p> <p>Secure Lock Guide Tube Sets are non-invasive products that have no direct patient contact.</p>	<p>The VariSource Reusable Transfer Guide Tubes are intended to connect between the VariSource Remote HDR Afterloader system and its range of applicators. This connection creates a conduit for the source wire to travel through and allows radioisotopes to be positioned within the patient's tumor site.</p>
SecureLock Fitting	VariSource Compatible	ClickFit/ClickFit Needle/Catheter/Luer
Tube Material	Fluorinated Ethylene Proplene (FEP)	Fluorinated Ethylene Proplene (FEP)
Sterility	None (No Body Contact)	None (No Body Contact)
Environmental Compatibility	MR Unsafe	CT/MRI Compatible

ii) Kobold Interstitial Extenders™

Information presented supports substantial equivalence of the Kobold Interstitial Extenders™ to the predicate device. The device has the same indications for use, has similar nature of body contact, is similar in shape and design, has the same fundamental technology and is also single use.

A. Predicate device name: Needle extenders

B. Predicate K-Number: K-051423

C. Comparison with predicate:

SUBSTANTIAL EQUIVALENCE TABLE	KOBOLD LLC	MICK RADIO-NUCLEAR®, INC.
K-Number	130757	051423
Device Description	Needle Extender Set	Needle Extender Set
Indications For Use	<p>The interstitial extenders have been developed to enable the connection of Varian or Kobold Transfer Tubes to Kobold Interstitial Needles. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient's tumor site. All Kobold Interstitial Extenders™ are intended for single use and are disposable.</p> <p>Interstitial Extenders are non-invasive products that have no direct patient contact.</p>	<p>The Mick HDR Interstitial Implant Accessories (consisting of needles, catheters, and fixation buttons) have been developed to function as accessories/applicators for the positioning of HDR Remote AfterLoader sealed sources in the interstitial treatment of cancer of the oral cavity, oropharyngeal tumors, head and neck and soft tissue sarcomas.</p>
Fitting	Kobold SecureLock transfer guide tube compatible	Luer
Needle Extender Material	Nylon 11, Nylon 12	Nylon
Sterility	None (No Body Contact)	None (No Body Contact)
Environmental Compatibility	MR Unsafe	CT/MRI Compatible

6.

Test Principle, Performance Characteristics:

FDA has not established special controls or performance standards for this device.

7.

Bench Top Testing:

Extensive testing in accordance with known standards is documented by the manufacturer. The standards are specifications for the materials used in surgical implant applications, predicate brachytherapy devices and manufacturer's acceptance procedures for finished devices.

8.

Conclusions:

i) Information presented supports substantial equivalence of the Kobold Secure Lock Transfer Guide Tube Set™ to the predicate device. The device has the same indications for use, has similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same cleaning and disinfecting procedures.

ii) Information presented supports substantial equivalence of the Kobold Interstitial Extenders™ to the predicate device. The device has the same indications for use, has similar nature of body contact, is similar in shape and design, has the same fundamental technology and is also single use.

Contraindications: As per clinical guidelines and standard clinical practice.

Warnings and Precautions: The precautions are provided in the device labeling for the Kobold device. There is no warning associated with this type of device.

9.

Summary:

Description	Comparison with Predicate
Biocompatibility	Safe as predicate - no patient contact
Performance Characteristics	Substantially equivalent
Intended Use	Substantially equivalent
Performance Tests	Not Required

The Kobold devices, based on the information submitted in this 510(k) application have been demonstrated to be substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Kobold, LLC
% Ms. Christine Bernstein
Regulatory Director
BB Medical Surgical, Inc.
2670 Leavenworth Street
SAN FRANCISCO CA 94133

April 3, 2014

Re: K130757

Trade/Device Name: Kobold Secure Lock and Luer Transfer Guide Tube Sets; Kobold
Luer Interstitial Extender Set

Regulation Number: 21 CFR 892.5700

Regulation Name: Remote controlled radionuclide applicator system

Regulatory Class: II

Product Code: JAQ

Dated: February 19, 2014

Received: February 21, 2014

Dear Ms. Bernstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

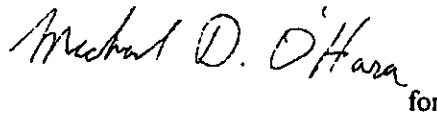
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Handwritten signature of Michael D. O'Hara in cursive script.

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130757

Device Name: Kobold Secure Lock Transfer Guide Tube Set™

Indications For Use:

The Secure Lock transfer guide tubes have been developed to enable the connection of Varian's VariSource iX and 200 afterloaders and other third party applicators. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient's tumor site.

Transfer guide tubes are non-invasive products that have no direct patient contact.

Device Name: Kobold Luer Transfer Guide Tube Set™

Indications For Use:

The Luer transfer guide tubes have been developed to enable the connection of Varian's VariSource iX and 200 afterloaders and other third party applicators that include a Luer style connection. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient's tumor site.

Transfer guide tubes are non-invasive products that have no direct patient contact.

Device Name: Kobold Luer Interstitial Extender Set™

Indications For Use:

The Luer interstitial extenders have been developed to enable the connection of Luer transfer guide tube to Kobold Interstitial Needles. This connection creates a conduit for the source wire to travel through and allows the radioactive isotopes to be positioned within the patient's tumor site.

Interstitial extenders are non-invasive products that have no direct patient contact.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Michael D. O'Hara

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